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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/755,016	01/05/01	WALKE	D LEX-0114-USA

024231 HM12/1026
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EXAMINER	
FRONDA,C	
ART UNIT	PAPER NUMBER
1652	8

DATE MAILED: 10/26/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/755,016	Applicant(s) Walke et al.
	Examiner Christian L. Fronda	Art Unit 1652

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on _____

2a) This action is **FINAL.** 2b) X This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) X Claim(s) *1-4* is/are pending in the application.

4a) Of the above, claim(s) *3 and 4* is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) X Claim(s) *1 and 2* is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____

* X See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

X Notice of References Cited (PTO-892)

6 and 7

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
   - I. Claims 1 and 2, drawn to an isolated nucleic acid molecule comprising at least 24 contiguous nucleotides of SEQ ID NO: 3 and an isolated nucleic acid molecule that encodes the amino acid sequence of SEQ ID NO: 4 and hybridizes under stringent conditions to SEQ ID NO: 3, classified in class 536, subclass 23.2.
   - II. Claim 3, drawn to an isolated nucleic acid molecule encoding the amino acid sequence of SEQ ID NO: 6, classified in class 536, subclass 23.2.
   - III. Claim 4, drawn to an isolated nucleic acid molecule encoding the amino acid sequence of SEQ ID NO: 2, classified in class 536, subclass 23.2.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I-III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Each of the products of Groups I-III are different nucleic acids with different nucleotide sequences and encode different proteins with different structures and amino acid sequences. Each of the products of Groups I-III are independent chemical entities and require different literature searches.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

3. During a telephone conversation with Lance K. Ishimoto on October 11, 2001, a provisional election was made with traverse to prosecute the invention of Group I, claims 1 and 2. Affirmation of this election must be made by applicant in replying to this Office action. Claims 3 and 4 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be [illegible]

5. Claims 1 and 2 are under consideration in this Office Action

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to all possible polynucleotides comprising at least 24 contiguous nucleotide of SEQ ID NO: 3 (claim 1) or all possible polynucleotides encoding any protein comprising SEQ ID NO: 4 (claim 2). The specification, however, only provides the following representative species encompassed by these claims: a polynucleotide consisting of a nucleotide sequence of SEQ ID NO: 3 and a polynucleotide encoding a protein consisting of an amino acid sequence of SEQ ID NO: 4. There is no disclosure of any particular structure to function/activity relationship in the disclosed species. The specification also fails to describe additional representative species of these polynucleotides by any identifying structural characteristics or properties other than the polynucleotide comprises at least 24 contiguous nucleotide of SEQ ID NO: 3 or the polynucleotide encodes any protein comprising SEQ ID NO: 4 for which no predictability of structure is apparent. The specification does not provide a written description of (1) the nucleotide sequence that is 5' or 3' of SEQ ID NO: 3 or 24 contiguous nucleotide thereof, and (2) the N-terminal of C-terminal amino acid sequence of a protein consisting of an amino acid sequence of SEQ ID NO: 4. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

8. Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid molecule comprising at least 24 contiguous nucleotide of SEQ ID NO: 3 and (2) any isolated nucleic acid molecule encoding any protein comprising SEQ ID NO: 4 and hybridizes under any stringent conditions to the nucleotide sequence of SEQ ID NO: 3. The specification does not enable any person skilled

in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized In re Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claims encompass (1) any isolated nucleic acid molecule comprising any 24 contiguous nucleotide of SEQ ID NO: 3 and (2) any isolated nucleic acid molecule encoding any protein comprising SEQ ID NO: 4 and hybridizes under any stringent conditions to the nucleotide sequence of SEQ ID NO: 3. The specification provides guidance and examples for an isolated nucleic acid molecule comprising at least 24 contiguous nucleotide of SEQ ID NO: 3 and encodes a serine protease and an isolated nucleic acid molecule encoding a protein comprising SEQ ID NO: 4 and having serine protease activity. While molecular biological techniques and genetic manipulation techniques are known in the prior art and the skill of the artisan are well developed, knowledge regarding the biological function, biological activity, or utility of (1) any isolated nucleic acid molecule comprising any 24 contiguous nucleotide of SEQ ID NO: 3 and (2) any isolated nucleic acid molecule encoding any protein comprising SEQ ID NO: 4 and hybridizes under any stringent conditions to the nucleotide sequence of SEQ ID NO: 3 is lacking. Thus, searching for the biological function, biological activity, or utility of said isolated nucleic acid molecule is well outside the realm of routine experimentation and predictability in the art of success in determining the biological function, biological activity, or utility of said nucleic acid molecule is extremely low.

The amount of experimentation to determine the biological function, biological activity, or utility of said nucleic acid molecule is enormous and entails (1) searching for any nucleic acid molecule that contains any 24 contiguous nucleotide of SEQ ID NO: 3, (2) searching for any nucleic acid molecule that encodes SEQ ID NO: 4 and determining the biological function, biological activity, or utility of the nucleic acid and encoded protein, or (3) determining the biological function, biological activity, or utility of any nucleic acid molecule that hybridizes to SEQ ID NO: 3 under any stringent condition. Since routine experimentation in the art does not include screening for a vast number of nucleic acid molecules, where the expectation of obtaining a desired biological [illegible]

[illegible] experimentation of [illegible] to those skilled in the art is undue.

Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the phrase "24 contiguous bases" renders the claim indefinite because the meaning of the phrase is not known. Amending the claim to recite such phrase as "24 contiguous nucleotides" would overcome the rejection.

In claim 1, the abbreviation "NHP" is vague and indefinite.

In claim 2, the phrase "hybridizes under stringent condition" renders the claim vague and indefinite because the specific hybridization and washing conditions are not recited in the claim.

Claim Rejections - 35 U.S.C. § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Tsuruoka et al.

Tsuruoka et al. teach a nucleic acid molecule which encodes a human serine protease and comprises at 26 contiguous nucleotides of SEQ ID NO: 3 (see Accession E13202, Alignment No. 1). Thus, the reference teachings anticipate the claimed invention.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. The fax phone number for this Group is (703)308-0294. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

CLF